UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,583	10/13/2000	Edgardo Delfino Carosella	195707USOPCT	8532

22850 7590 09/24/2002

OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT PC
FOURTH FLOOR
1755 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202

EXAMINER
CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
1637	16

DATE MAILED: 09/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/622,583	Applicant(s) CAROSELLA ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-13 and 16-23* is/are pending in the application.

4a) Of the above claim(s) *4-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3 and 16-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No. 15) filed on June 25, 2002 has been entered.

2. Applicants' request for a signed copy of IDS is considered and a signed copy is enclosed herewith this office action.

Response to Arguments

3. Applicant's response to the office action (Paper No.15) is fully considered and deemed persuasive in part.

4. The rejection made under 35 U.S.C. 112 second paragraph in the previous office action is withdrawn herein in view of the applicants' amendment (Paper No.15).

5. The following is the rejection made in the previous office action under 35 U.S.C. 102(b):

Claims 2-3 and 14-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bensussan et al. (Proc.Natl.Acad.Sci.USA., 92: 10292-10296, 1995).

Bensussan et al. teach a method for detecting membrane-bound HLA-G expression wherein Bensussan et al. disclose that the method comprises (i) removing a tumor sample (see page 10293, column 1, lines 8-14, and table 1); (ii) performing indirect immunofluorescence on the sample (see page 10293, paragraph 4); (iii) labeling the cells of the sample with antibodies for HLA-G (see page 10293, column 1, paragraph 4and column 2, paragraph 4). Bensussan et al. further teach lysing the labeled cells and contacting the lysed cells with HLA-G antibodies and detecting the immunoprecipitates for HLA-G expression profile (see page 10294, column 1, paragraph 2). Bensussan et al. teach monoclonal antibodies of HLA-G membrane bound and soluble isoforms (see page 10294, column 1, paragraph 2); and detection of HLA-G expression

(immunoprecipitates) by SDS/PAGE electrophoresis (see page 10294, column 1, paragraph 2). Thus, the disclosure of Bensussan et al. meets the limitations in the instant claims.

Response to Arguments:

Applicants' arguments with respect to the rejection made under 35 U.S.C. 102(b) have been considered and are found not persuasive. Applicants argue that the method comprises solid tumor and tumor sample itself whereas, the prior art of the record (Bensussan et al.) uses cultured cells. This is found not persuasive because Bensussan et al. also uses tumor sample from a T-lymphoma patient and the tumor cells were cultured (TC9 cells) and used for analysis of HLA-G expression profile (see page 10293, column 1, lines 11-15). Applicants' also argue that the Bensussan et al. did not teach establishing the HLA-G expression profile, which is found not persuasive because Bensussan et al. teach the HLA-G expression in various HLA-G expressing and nonexpressing cells and confirming HLA-G expression (see page 10294, column 1, paragraph 2). Hence the method as disclosed in the prior art of the record inherently teaches establishing HLA-G expression profile in various cells. Therefore, the prior art of the record meets each of the limitations found in the claims. Further, the claim is of the open "comprising" format, which permits the inclusion of additional elements, so that any additional steps are permitted in the claim. Therefore the rejection is maintained herein.

New issues

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3, and 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite

for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 is indefinite in the recitation of the term 'optionally'. It is unclear whether the term is a critical limitation or not, i.e. the method comprises labeled tumor cells or comprises non labeled cells. Therefore, the metes and bounds of the claim are unclear. Claims 3, 19-23 are rejected sofar as they depend on usage of the term optionally in the instant claims.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
September 20, 2002

JEFFREY FREDMAN
PRIMARY EXAMINER